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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,389	10/29/2003	Lawrence T. Boni	TRA-00801	6398

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
11/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,389	BONI ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,14-16,26 and 29-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,14-16,26 and 29-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-27-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and declaration dated 7-28-08 is acknowledged.

In view of the amendment, the previous rejections are withdrawn.

Claims included in the prosecution are 1, 14-16, 26, 29-53.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 14-16, 26, 29-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coe et al (5,540,936) in combination with either Gonda (US 2005/00199260 or Lagace (5,662, 929) individually or in combination.

Coe teaches liposomes containing phosphatidylcholine and cholesterol and amikacin. One of the phospholipids taught is DPPC (col. 4, line 24; col. 7, line 51; examples). The lipid: drug ratios are taught on col. 6, lines1-7). What are lacking in Coe are the use of the composition for the treatment of pulmonary infections and the mode of administration. Coe however, on col. 12, line 60 et seq., teaches that the mode of administration of the preparation may determine the sites and cells in the organism to which the compound is delivered.

Gonda et al while disclosing liposomal formulations containing amino glycosides.

According to Gonda et al, such formulations can be used for treatment of bacterial diseases in cystic fibrosis patients. The amino glycosides include amikacin. The composition is administered by pulmonary route (0011, 0027, 0060-0066, 0070 and 0089). Further according to Gonda, aerosol administration would result in targeted deposition of the composition in the desired parts of the respiratory tract (0074-0077). Gonda does not teach the lipid to drug ratios.

Lagace teaches that chronic lung infection due to P. aeruginosa is a major cause of morbidity and mortality in patients with cystic fibrosis. According to Lagace P aeruginosa colonizes more than 90 % cystic fibrosis adolescents. Lagace teaches the encapsulation of amikacin in liposomes for the treatment of P. aeruginosa infections. One of the modes of administration taught by Lagace is aerosol (abstract, col. 3, line 7 through col. 6, line 16; col. 7, line 40 through col. 8, line 15; Examples).

It would have been obvious to one of ordinary skill in the art to administer the composition of Coe pulmonarily to treat lung infections caused by bacteria such as P. aeruginosa with a reasonable expectation of success since Coe teaches that the mode of administration depends on the site of infection and Gonda and Lagace teach the use of amikacin is effective against pulmonary bacterial infections.

What is also lacking in Lagace is the claimed protocol of administration as claimed in instant claims. However, whether the composition has to be administered daily or once a day and the dosage depend upon the severity of the condition, the age of the patient and other parameters, they are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results.

Applicant's arguments have been fully considered, but are deemed to be moot in view of the new rejection. The declaration has been fully considered, but is not persuasive. First of all, instant independent claim does not recite cystic fibrosis and does not specify what bacteria the biofilm is made of. On page 866, col. 1, Meers (exhibit A) states that each type of biofilm is distinct with respect to its physicochemical characteristics as are various types of liposomes. In essence the data is not commensurate with the scope of the claims.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is

(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK